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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/857,465 | 06/05/2001 | David O'Hagan | P66645US0 | 5256 |

136 7590 11/19/2003

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EXAMINER

DAVIS, BRIAN J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1621

DATE MAILED: 11/19/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,465

Applicant(s)

O'HAGAN, DAVID

Examiner

Brian J. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 12-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 22 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election (Paper No. 6), without traverse, of Group IV (claim 11) and compound 8 on page 21 as the Group and species, respectively, elected for prosecution is acknowledged. The examiner notes for the record that new claim 22 is drawn exclusively to the elected species and so will be included in Group IV. All other claims are withdrawn from consideration as being drawn to non-elected subject matter. The election/restriction is hereby made FINAL.

Claim Objections

Claim 22 is objected to because of the following informalities: the claim lacks a period after the structure. Claims must begin with a capital letter and end with a period. MPEP 608.01(m). Appropriate correction is required.

Claim Rejections - 35 USC § 103

The elected species has been searched and is not deemed free of the prior art.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11 and 22, in so far as they read on the elected species, are rejected under 35 U.S.C. 103(a) as being unpatentable over *Arch. Immunol. Therapii Doswiadczalnej* (1961), 9(4), p. 609-29 (CAPLUS abstract).

The elected species is one of only two possible enantiomers of an old and well-known compound in the chemical arts: RN=94964-58-6. The cited reference explores the structure/activity relationship in the pheylisopropylamine group with respect to the central nervous system of mice. That is, the elected species is used in a biological setting.

It is well-established that the expectation with regard to enantiomers is that activities as they pertain to living systems are expected to be different. *In re Adamson*, 275 F.2d 952, 125 USPQ 233 (CCPA 1960). The fundamentals of optical activity and stereoisomerism are well known to persons of ordinary skill in the art. One of ordinary skill would have immediately envisioned the resolution of the racemic mixture and would have been motivated to do so with the reasonable expectation that the two resulting enantiomers would have substantially different pharmacological activity. This is an expected result and it is well established that expected beneficial results are evidence of

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obviousness, just as unexpected beneficial results are evidence of unobviousness. *In re Skoll*, 523 F.2d 1392, 187 USPQ 481 (CCPA 1975); *In re Skoner*, 517 F.2d 947, 186 USPQ 80 (CCPA 1975); *In re Gershon*, 372 F.2d 535, 152 USPQ 602 (CCPA 1967).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 703-305-7129. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-4532. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.



BRIAN DAVIS
PRIMARY EXAMINER

Brian J. Davis
November 11, 2003